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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,322	09/12/2006	Birgit Baumgarten	4-33201A	4964

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
04/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,322	BAUMGARTEN ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7 and 10-18* is/are pending in the application.

4a) Of the above claim(s) *5, 6, 10-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/17/2010 has been entered. Claims 5-7 and 10-18 are pending. Claims 7 and 16-18 are under consideration. All other claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Withdrawn Objections and/or Rejections

The rejection of claims 7 and 16-18 under 35 U.S.C. 112, second paragraph for referring to the commercial database is withdrawn in view of amended claims.

The rejection of claims 7, 17, and 18 under 35 U.S.C. 102(e) as being anticipated by Yang et al. (US Patent No. 6,919,176 B2, Jul. 19, 2005; 102(e) date: May 7, 2001) is withdrawn in view of amended claims.

The rejection of claims 7, 17, and 18 under 35 U.S.C. 102(e) as being anticipated by Logan et al. (US 2003/0109044 A1, June 12, 2003; 102(e) date: Oct. 16, 2001) is withdrawn in view of amended claims.

Claim Rejections under 35 USC § 112, 1st paragraph

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 7 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for screening for a candidate compound that antagonizes or agonizes a GPR4 related polypeptide comprising the amino acid sequence of SEQ ID NO: 3, does not reasonably provide enablement for a method for screening for a candidate compound that antagonizes or agonizes a GPR4 related polypeptide comprising an amino acid sequence that is at least 95% identical the amino acid sequence of SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in

the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 7 is drawn to a method for screening for an agonist or antagonist of a GPR4 related polypeptide comprising the amino acid sequence of SEQ ID NO: 3. Claims 16-18 depends from claim 7. Since there is no functional limitation or any particular conserved structure recited in the claims, the method recites an unreasonable number of inoperative polypeptides, which the skilled artisan would not know how to make and/or use.

The specification discloses a human GPR4 polypeptide of SEQ ID NO: 3 and a method using the polypeptide to screen an agonist or antagonist (Example 10). However, other than the human GPR4 polypeptide of SEQ ID NO: 3, the instant disclosure does not provide sufficient guidance/direction or working examples on the structural and functional requirements commensurate in scope with what is encompassed by the instant claims. There are no working examples of using polypeptides that are less than 100% identical to the polypeptide SEQ ID NO: 3. The instant disclosure does not show (i) which portions of the human GPR4 polypeptide of SEQ ID NO: 3 are critical to its activity; and (ii) what modifications (e.g., substitutions, deletions or additions) one can make to SEQ ID NO: 3 will result in a mutant or a fragment with the same functions as the polypeptide set forth in SEQ ID NO: 3.

It is unpredictable whether a variant or homologue of SEQ ID NO: 3 would retain the same function as that of the full length of polypeptide of SEQ ID NO: 3. The state of the art (See, e.g., Ngo, et al, *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz, et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495) is such that the relationship between sequence of a protein and its activity is not well understood and is not predictable. Excising out portions of a protein or modifications to a protein, e.g., by substitutions or deletions, would often result in deleterious effects to the overall activity and effectiveness of the protein. The prior art teaches a human GPR4 polypeptide (see, e.g., Mahadevan et al., Genomics 30:84-88, 1995; Yang et al., US Patent No. 6,919,176 B2). However, the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to make and use *the recited genus* of polypeptides in the claimed methods. In this respect, it is noted that the specification discloses that SPC, which is reported to be a ligand for GPR4, does not modulate pH-dependent stimulation and does not activate cAMP formation on its own (page 41, the 2nd paragraph of the specification). Thus, in view of the nature of complexity of the work and unpredictability of the art, it would take undue experimentation for one skilled in the art to make and use the claimed methods of polypeptides without sufficient guidance, working examples, and knowledge about functions of encompassed polypeptides structurally related to SEQ ID NO: 3.

Accordingly, while being enabling for a method for screening for an agonist or antagonist of a human GPR4 polypeptide comprising the amino acid sequence of SEQ

ID NO: 3, does not reasonably provide enablement for a method for screening for a candidate compound that antagonizes or agonizes a GPR4 related polypeptide comprising an amino acid sequence that is at least 95% identical the amino acid sequence of SEQ ID NO: 3.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
April 13, 2010